

CHAPTER I

INTRODUCTION

A. Background

On January 30, 2020, the World Health Organization (WHO) declared Corona Virus Disease-19 (COVID-19) a global emergency. Continuing on March 11, 2020, WHO has upgraded the status of the spread of COVID-19 to a pandemic, this is a sign that the Covid-19 virus has spread throughout the world and has attacked many people worldwide. All countries in the world were affected and experienced changes in conditions. Many countries have declared a national emergency to limit the spread of the virus, and as advised by WHO in terms of implementing social restrictions with significant consequences for society and the economy.

The existence of this COVID-19 pandemic requires a global collaborative response to overcome it. The provision of medicines, vaccines, and other medical devices is needed to restore the condition of all mankind. As stated by WHO, world governments need to pay attention to increasing global solidarity on health issues while facing a health crisis due to a pandemic. Actions needed include accelerating access to drugs, tests, and vaccines for COVID-19, implementing a health paradigm for all countries, overcoming healthcare inequity conditions, and implementing global leadership based on science and data (Sebayang, 2021).

The health crisis due to the COVID-19 pandemic has increased the urgency in addressing urgent global health access challenges fairly. However, the condition created when the Covid-19 pandemic hit the world was scarcity and lack of access to medical products. Since the beginning of the pandemic, many large countries have continued to restrict exports. For example, the US had given an export ban to 3M companies (Minnesota Mining and Manufacturing Company) because they had to meet US domestic needs, the US had also secured supplies of Remdesivir drugs, namely drugs that were considered effective in Covid-19 treatment is for the country only (IGJ, 2021). Even when vaccines began to be found, large countries continued to make restrictions. Developed countries secured vaccine supplies that exceeded their needs, even though developing countries had difficulty getting adequate vaccine supplies (IGJ, 2021). As was done by the EU, which had imposed a ban on the export of the AstraZeneca vaccine following the inability of one of the Big Pharma to meet the needs

of the European Union on time (IGJ, 2021). In particular, developing countries face serious challenges in accessing medical products in this virus outbreak prevention strategy.

Vaccination is one of the methods used in eradicating a pandemic. Thus, with the discovery of a vaccine, it will become a critical commodity targeted in various countries because it has high selling power. Indeed, the discovery of a vaccine must be protected by a legal instrument known as Intellectual Property Rights (IPR), namely through patents. Vaccines result from human intelligence because manufacturing requires a long process, uses thinking power, and costs much money (Giovanni & Atmadja, 2022). The process of making vaccines is repeated (trial & error) until it reaches the stage of successfully forming a vaccine formula that can significantly increase immunity in the human body. All work produced by human intellectuals can be protected by the state with the application of Intellectual Property Rights (IPR), especially on products registered under the type of Patent Rights. The conditions for a matter to be legally protected so that it is allowed to monopolize its findings are regulated internationally in the TRIPs (Trade-Related Aspects of Intellectual Property Rights) rules.

The COVID-19 vaccine is a new creation and a product needed in the global crisis due to the pandemic. The costs used in the research and development process for essential medicines are large, as well as the high expenditure on research costs used as a significant investment must return through relatively high-profit margins. The value is because there is a desire for patent registration on a product, namely so that the patent owner can set the price of the desired product and also have the right to prohibit other parties from using their patents without permission (Giovanni & Atmadja, 2022).

Several big countries are trying to create a COVID-19 vaccine, including the United States, China, Russia, Australia, Britain, and Germany. The discovery of vaccines by these countries is used as the first step in an excellent superpower trade war, this can happen because vaccines have economic value and legal aspects that protect them due to human intellectual work (Fatizah, 2022). Given the existence of such protection, it is considered that intellectual property rights have become the main obstacle factor related to the affordability of access to vaccines, drugs, and technology, especially for developing countries.

The existence of an agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the context of dealing with the COVID-19 outbreak has

been identified as one of the significant obstacles to the accessibility of equitable distribution of vaccines and medicines in every country in the world, especially for developing countries (Chattu, Singh, Kaur, & Jakovljevic, 2021). The enforcement of

TRIPS as a hard legal instrument is binding in securing patent protection for pharmaceutical products for up to 20 years, and any violation results in trade sanctions.

The evident from the data recorded by World Health Organization (WHO), that the distribution of the COVID-19 vaccine experienced a significant inequity. Of the 700 million doses of vaccine that have been distributed until April 2021, it was noted that less than 1 million doses of vaccine were given to developing or poor countries. Meanwhile, 500 million doses of vaccine have been distributed to China and the US (Widi, 2021). The existence of provisions on the protection of intellectual property rights encourages the practice of monopoly knowledge controlled by the pharmaceutical industry in developed countries. This is where a form of abuse arises from the protection of IPR by using IPR law to prevent other parties from producing and trading products whose technology is requested for such protection to try to keep profits in the hands of IPR holders. In the issue of Health and drug access, the existence of patent protection can create uncertainty and increase costs, delay competition and keep prices high for low- and middle-income countries or developing countries, and in the end, this becomes a barrier to public access to receive medicines, medical devices, including vaccines, which are needed by the public at large are important, especially during a pandemic situation (Rachmi Hertanti & Prakoso, 2021).

Given the large number of victims and suffering in all countries in the world caused by COVID-19, India has raised this issue as an issue in its global Health diplomacy, in addition to submitting a Joint South African proposal addressed to the WTO in submitting a temporary waiver of IPR to ensure affordability and timely access to COVID-19 medical products to all countries. India and South Africa on October 2, 2020, faced the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council in submitting the proposal. Submission of this proposal is not only in the interest of India and South Africa but also for developing countries or other poor countries in achieving equitable access to vaccines and other medical products.

Taking into account the current global emergency, WTO members need to cooperate in ensuring that intellectual property rights do not become a barrier to timely access to affordable vaccines, medicines, development, and all related support eradication of the COVID-19 outbreak for all countries in the world (Fatizah, 2022).

With the submission of the TRIPS Waiver Proposal, there is great hope for WTO members to properly consider and agree on the urgency of global health equity. Based on the TRIPS rules, if faced with extraordinary circumstances, the Conference of Ministers can decide to waive the obligations imposed on WTO members. Therefore, it would be good if the temporary waiver of intellectual property rights for vaccines and other health products put forward in the proposal for handling COVID-19 was realized. Considering the global health crisis and the extraordinary situation, extraordinary cooperation between countries is also needed. Humanitarian action is more needed than the interest of accumulating profits in this handling.

B. Research Question

Based on the background of the problems described above, the research question that the author will discuss is “Why TRIPS Waiver Proposal, as a way to deal with COVID-19, is still problematic and is not fully accepted by the whole of WTO member states?”

C. Purpose of Research

The author of this study aims to find out whether the submission process of the TRIPS Waiver Proposal proposed by India and South Africa can be a success in fighting for equitable distribution of health facilities in the context of the COVID-19 pandemic until in the end of 2022.

D. Theoretical Framework

1. Intellectual Property Rights (IPRs)

Currently, the development of international regimes is very rapid in international relations. Stephen D. Krasner states that the international regime is an order in which there is a collection of principles, rules, norms, and explicit and implicit decision-making processes, these decisions can be related to the expectations of the actors and also contain the interests of the actors themselves in international relations (Krasner, 1983). Stephen D. Krasner also stated that the implications of a regime are not only towards the norms that facilitate the mere creation of Cooperation but also have implications for a form of Cooperation that is more than internal interests in the short term (Krasner, 1983). So, when analyzing

the effectiveness and processes of an international regime that develops in international politics apart from negotiations at the international level by each country's representative, the role of negotiations at the national level of each country is also very important because it involves the process of ratifying the formation of regulations into law. the statute, then every element of the government and society must analyze this from every form of the country's national interests.

With the development of the times, trade in various commodities can occur at the global level, making the existence of intellectual property no exception to this. IPR is a form of legal protection regime for intellectual property in the form of inventions in the fields of technology, science, arts, and literature, a distinguishing mark of a product of goods and services (Ferianto, 2021). The rights that people give to creative works of their minds are known as intellectual property rights. Usually, Intellectual Property Rights (IPR) will give the creator the exclusive right to use a work for a certain period of time (WTO, 2022) Intellectual Property Rights were indeed born and developed in western countries because these countries are dominated by developed countries which usually act as producing countries and as owners of Intellectual Property Rights (Ferianto, 2021).

Intellectual property in terminology certifies that intellectual property is the result of intellectual activity, and that intellectual property rights can be protected by law. The law that protects intellectual property is territorial, but the law is universal in scope, so almost all countries in the international world refer to this system. IPR registration and law enforcement are indeed separate in each country, but these legal differences over time are increasingly harmonized with various international agreements, for example, the Trade Related Aspect of Intellectual Property Rights (TRIPS) Agreement by the World Trade Organization (WTO) or 21 international agreements (6 on copyright and 15 on industrial assets) administered by the World Intellectual Property Organization (WIPO), besides that there are also other agreements that allow the registration of IP in more than one country (jurisdiction) simultaneously (Wijaya, 2012).

Currently, separate laws in the constitutions of countries around the world generally refer to as "Intellectual Property Rights". Indeed, the existence of IPR can protect the benefits of industry, but in a pandemic, human health and welfare must be prioritized because in reality, what is happening is that capitalism is a patented product made by big and rich countries.

The implementation of intellectual property (IP) provisions in free trade agreements serves to create a guarantee of protection for the creation of works of art and goods, such as the creation in the case of drugs which in the process requires high costs in the form of investments used to carry out research and development (R&D) processes (Islam, et al., 2019). R&D costs arise after a patent on the drug is granted, and usually arise early in the clinical development process. IP provisions limit the use and marketing of that items while also giving investors/creators exclusive rights to recover their sunk costs during clinical research (Islam, et al., 2019). However, because of the protection of these drugs has encouraged the opportunity to create monopoly markets between rich and poor countries.

2. The Norm Life Cycle

The definition of a norm is a single rule that controls behavior. Martha Finnemore and Kathryn Sikkink have created a norm concept called the norm life cycle. This concept explains that norms will bring a shift to a change in a system or an order. Like the spark of an idea that then turns into a norm and develops into something that is widely accepted through a process that passes through three cycles of levels. The stages in this process are the first, norm emergence, the second, norm cascade, and the third, norm internalization (Finnemore & Sikkink, 1998).

1) The first stage of the cycle is norm emergence. In this stage, two elements synergize with each, namely the norm entrepreneur and organizational platforms.

i) Norm entrepreneur

A Norm entrepreneur is an actor who has a strong idea or notion in trying to create a new norm with consideration of the logical consequences because of the condition of the old norms that are currently developing. Usually, the entrepreneur norm will bring a follow-up framework and new norms, as a counter form of the old norm and based on an interest that is brought in to be introduced to a system (Richter, 2017). Norm entrepreneur creates new norms as a form of empathy or an ideational commitment. Norm entrepreneurs have an important role in carrying out issue framing, which is related to the formation of an issue. Usually, norm entrepreneurs use an organization as a medium in promoting the new norms they want to spread. Persuasively, the norm entrepreneur has the goal of convincing the wider community to accept the norms being promoted. The position of the

norm entrepreneur is very vital in the formation of norm internalization in a system because the norm entrepreneur is an actor who builds new ideas that will be made into a norm and implemented in a system to become a solution to global problems.

ii) Organizational Platforms

An organizational Platform is a container that is used as a promotional system by norm entrepreneurs. As mentioned by (Finnemore & Sikkink, 1998) the salient features of modern organizations and an important source of influence for an international organization are regarding the use of expertise and information in changing the behavior of other actors in the organization. This is related to professionalism regarding empirical studies that can help or even prevent the emergence of new norms in international organizations. In most cases in this process, emergency norms can move to the next stage if these norms are successfully institutionalized in a set of rules in international organizations. Norm entrepreneurs usually need support from state actors in supporting the norms they carry, and to achieve the next level, they must reach a tipping point. Persuasion carried out by Norm Entrepreneurs is said to be successful if the norm can be adopted by the critical mass. The critical mass in question is the power of countries that adopt these norms. According to the argument (Finnemore & Sikkink, 1998), critical mass can be achieved if at least approximately 1/3 of the countries in the system are willing to start adopting the norms they carry. This tipping point is the boundary for the norm emergence and norm cascade phases.

- 2) The second stage is the norm cascade, this stage is marked after the tipping point, there is an increase in countries that accept the norm so that new dynamics are created. As has been adopted by (Finnemore & Sikkink, 1998), the existence of international or regional influence that spreads bring the influence of norms in the international world to occupy positions that are more important than domestic politics. The mechanism in the form of active international socialization at this stage is expected to encourage norm breakers to form norm followers. There are two ways to become a socialization agent. The first is to hit targets in adopting new policies and laws and ratifying agreements. The second way is to monitor compliance with international standards, at this stage,

the norm leader (the country that first adopted the norm) persuades other countries to follow the existing norms. As stated by (Finnemore & Sikkink, 1998) that the basis for a country to want to adopt the norms that are spread is due to a relationship with an identity as a member of a certain social category. In addition, there are three motivations for the state to submit to norms, namely legitimacy, respect, and conformity. This legitimacy affects the role of wishing in the behavior of the state, for example, international organizations as labelers accept or reject, or when the state builds a domestic perception of its citizens, whether the country is better than other countries in making a decision. Whereas the motivation of respect and conformity is in the form of an assessment in building relations between countries in a community. Conformity in a community can be interpreted as a state's social evidence in adopting norms, while respect concerns legitimacy and conformity, respect itself can show that a country's leaders adopt norms to want to be judged well by other countries and also, they want to assume that their country is doing an image the good one.

- 3) The third stage is internalization. This cycle is marked that the norms that have been accepted and taken for granted. Thus, this condition is considered to no longer debate the norms socialized by the international community. According to (Finnemore & Sikkink, 1998), the norms that have been internalized then institutions appear that aim to perpetuate the truth of these norms.

E. Argument

Based on the background and support from the framework and problem formulation, the author can draw an argument that so far, the process of the TRIPS Waiver proposal submission to the WTO from the beginning of 2020 until 2022 is still problematic and is not fully accepted by the whole of WTO member states. This happened because, based on the implementation of the norm life cycle concept, norm internalization has not been fully formed since most of the big countries in the WTO members have yet to agree on all the aspects of the TRIPS Waiver proposal submitted by India and South Africa. The provisional decision only stops on the vaccine, but other aspects, such as diagnostics and therapeutics, are still being postponed. Even though the tipping point of supporters has exceeded 1/3, full support is needed for the success of the TRIPS Waiver Proposal because voting in the WTO is based on consensus.

F. Research Method

1. Research approach

The approach used in this paper is qualitative, and the type of research approach used is descriptive. This method uses a method of describing and interpreting something. For example, existing conditions or relationships, responses from various parties, ongoing processes, consequences that occur, or ongoing trends that can be adapted to concepts known in the literature on International Relations so that a research conclusion can be drawn.

2. Data source

Sources of data used in this paper are secondary data sources derived from previous research in books, news, and journal articles from various scientific journals related to the issues discussed, found on internet sites.

3. Data collection technique

The data collection technique used a literature study, namely by collecting data and information related to the problem under study in the form of books, journal articles, official documents, the internet, and news.

4. Data analysis technique

The data analysis technique used by the author in analyzing the data obtained from this research is descriptive qualitative. Describing the problem based on the facts that exist and then connecting the facts. In contrast, the writing method that the author uses is the deductive method, where the author begins the discussion by describing the problem in general and then specifically describing the consequences of the previously described problems.

G. Range of Research

In writing this scientific paper, the author limits the focus of the discussion thus that the objectives can be achieved and remain following the title that has been presented. The scope of the research is from the first submission of the TRIPS Waiver proposal to the WTO in the context of health equity which will run until 2022.

H. Writing Systematic

The writing of this thesis is arranged systematically based on the rules that apply in scientific writing and divided into several chapters, with discussions in their own but

interconnected areas. The aim is to make it easier to interpret the topic of the problem. Therefore, this thesis is divided into three chapters as follows:

CHAPTER 1 INTRODUCTION

This chapter contains an introduction covering the background of the problem, problem formulation, framework of thought, hypotheses, research objectives, research scope, research methods, and writing systematics

CHAPTER 2 THE TRIPS WAIVER RUNNING PROCESS

This chapter will explain the chronology and the dynamics of the responses of various parties to the submission of the TRIPS Waiver proposal process

CHAPTER 3 CASE IMPLEMENTATION ON THE CONCEPT OF THE NORM LIFE CYCLE

This chapter will implement the concept of the norm life cycle theory that was coined by Martha Finnemore and Kathryn Sikkink in the struggle for the TRIPS Waiver proposal as a new norm in the context of equitable distribution of COVID-19 pandemic health for all countries

CHAPTER 4 CONCLUSION

This chapter concludes the discussion from the previous chapters